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| FORM PTO-1449<br>INFORMATION DISCLOSURE STATEMENT |    |                    |           | ATTY DOCKET NO.<br>20784/4        |       | SERIAL NO.<br>09/745,776 |                         |
|---|----|--------------------|-----------|-----------------------------------|-------|--------------------------|-------------------------|
|   |    |                    |           | APPLICANT(S): Demuth et al.       |       |                          |                         |
|   |    |                    |           | FILING DATE:<br>December 22, 2000 |       | ART UNIT:<br>1614        |                         |
| UNITED STATES PATENT DOCUMENTS                    |    |                    |           |                                   |       |                          |                         |
| EXAM.<br>INITIAL                                  |    | DOCUMENT<br>NUMBER | DATE      | NAME                              | CLASS | SUB<br>CLASS             | FIL.<br>DATE IF<br>APPR |
| 1   | AA | 3,174,901          | 3/23/65   | Sterne                            | 167   | 65                       |                         |
|   | AB | 3,879,541          | 4/22/1975 | Kabbe et al.                      | 424   | 326                      |                         |
|   | AC | 4,028,402          | 6/7/1977  | Fischer et al.                    | 260   | 501.14                   |                         |
|   | AD | 5,462,928          | 10/31/95  | Bachovchin et al.                 | 514   | 19                       |                         |
|   | AE | 5,543,396          | 8/6/96    | Powers et al.                     | 514   | 19                       |                         |
|   | AF | 5,939,560          | 8/17/99   | Jenkins et al.                    | 548   | 535                      |                         |
| FOREIGN PATENT DOCUMENTS                          |    |                    |           |                                   |       |                          |                         |
|   |    | DOCUMENT NUMBER    | DATE      | COUNTRY                           | CLASS | SUB<br>CLASS             | TRAN<br>YES/NO          |
| 1   | BA | WO 01/62266 A2     | 08/30/01  | PCT                               | A61K  | 38/00                    | Y                       |
|   | BB | WO 00/01849        | 01/13/00  | PCT                               | C12Q  | 1/68                     | Y                       |
|   | BC | DD 296 075 A5      | 11/21/91  | Germany                           | C07D  | 295/04                   | Y                       |
|   | BD | EP 0 995 440 A1    | 4/26/00   | EPO                               | A61K  | 31/425                   | N                       |
|   | BE | WO 91/11457        | 08/8/91   | PCT                               | C07K  | 7/34                     | Y                       |
|   | BF | WO 91/16339        | 10/31/91  | PCT                               | C07K  | 5/10                     | Y                       |
|   | BG | WO 98/19998        | 5/14/98   | PCT                               | C07D  | 207/00                   | Y                       |
|   | BH | WO 91/17767        | 11/28/91  | PCT                               | A61K  | 37/54                    | Y                       |
| 2   | BI | JP 04-288098       | 10/13/92  | JP                                | C07K  | 7/06                     | (Abstract<br>Only)      |

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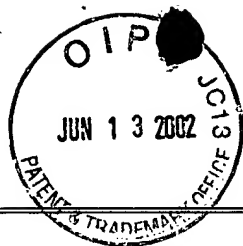
TECH CENTER 1600/2900

Demuth et al.

09/745,776

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Page 2 of 4



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## OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

|    |   |
|----|---|
| CA | The Merck Index, 12 <sup>th</sup> Edition, An Encyclopedia of Chemicals, Drugs, and Biologicals, 1996, Page 1014.   |
| CB | Martindale The Extra Pharmacopoeia, 30 <sup>th</sup> Edition, London Pharmaceutical Press, 1993, Page 36.   |
| CC | DURINX, C.; et al.; "Reference Values for Plasma Dipeptidyl-Pepidase IV activity and their Association with Other Laboratory Parameters". Clin Chem Lab Med 2001, February; 39 (2) :155-9, 1 page.  |
| CD | GOSSRAU, R.; "Cytochemistry of Membrane Proteases". Histochem J, 1985, July; 17 (7) :737-71, 1 page.  |
| CE | HAHN, T.; et al.; "Enzyme Histochemical Evidence for the Presence of Potential Blood Pressure Regulating Proteases in Cultured Villous Explants from Human First Trimester Placentae". Acta Histochem 1993, December, 1995 (2) :185-92, 1 page.               |
| CF | HEYMANN, E.; et al.; "Has Dipeptidyl Peptidase IV an Effect on Blood Pressure and Coagulation." Klin Wochenschr, 1984, January, 2;62 (1) :2-10, 1 page.   |
| CG | MAGYAR, C.E.; et al.; "Proximal Tubule Na Transporter Responses are the same during Acute and Chronic Hypertension." Am J Physiol Renal Physiol, 2000, August; 279 (2) :F358-69, 1 page.  |
| CH | PAPIES, B.; et al.; "Isoenzyme (Lactate Dehydrogenase, Aspartate Aminotransferase) and Dipeptidyl Peptidase IV Activity Changes in Blood Plasma Likely Indicative of Organ Involvement due to Arterial Hypertension." Cor Vasa, 1991; 33 (3) :218-26, 1 page. |
| CI | QURESHI, N.U.; et al., "Endogenous Neuropeptide Y Mediates Vasoconstriction during Endotoxic and Hemorrhagic Shock". Regul Pept, 1998, September 25; 75-76:215-20, 1 page.  |
| CJ | Index Nominum, International Drug Directory 1992/1993, Medpharm Scientific Publishers, pages 728-729.   |
| CK | The Merck Index, An Encyclopedia of Chemicals and Drugs, 9 <sup>th</sup> Edition, Merck & Co., Inc., 1976, page 773.  |
| CL | C.J. Bailey et al., <u>New Antidiabetic Drugs</u> , Smith-Gordon Nishimura, 1990, p. 36.  |
| CM | C.B. Welch, <u>Medical Management of Non-Insulin-Dependent (Type II) Diabetes</u> , 3 <sup>rd</sup> edition, American Diabetes Association, "Diagnosis and Classification" p. 3, 1994, Pharmacologic Intervention (1 page).                                   |
| CN | Mannucci et al., <u>Diabetes Care</u> , "Effect of Metformin on Glucagon-Like Peptide 1 (GLP-1) and Leptin Levels in Obese Nondiabetic Subjects", 24(3): 489-494, March 2001.   |
| CO | Stryer, <u>Biochemistry 3<sup>rd</sup> Ed.</u> , "Protein Conformation, Dynamics, and Function", 1988, p 191-193.   |




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|--|-----|---|
| h  | CP  | Pauly et al., <u>Regulatory Peptides</u> , "Abstracts Issue: Abstracts from the 11 <sup>th</sup> International Symposium on Regulatory Peptides", July 15, 1996, 64(1-3): 148 plus cover.   |
|  | CQ  | Gutniak et al., <u>New England Journal of Medicine</u> , "Antidiabetogenic Effect of Glucagon-like peptide-1 (7-36) Amide in Normal Subjects and Patients With Diabetes Mellitus", 1992, 326: 1316-1322.  |
|  | CR  | H.A. Smith et al., <u>Veterinary Pathology</u> (fourth edition), "Diseases and Disorders of Metabolism: Deficiency Diseases", 1972, p 1018-1020.  |
|  | CS  | G.G. Duncan, <u>Diseases of Metabolism (Asian edition)</u> , "Diabetes Mellitus", 1966, p 951-957.  |
|  | CT  | T.J. Kieffer et al., "Degradation of Glucose-Dependent Insulinotropic Polypeptide and Truncated Glucagon-Like Peptide 1 In Vitro and In Vivo by DP IV", <u>Endocrinology</u> , Vol. 136(8), 1995, p 3585-3596.  |
|  | CU  | C.F. Deacon et al., <u>Diabetes</u> , "Both Subcutaneously and Intravenously Administered Glucagon-Like Peptide I Are Rapidly Degraded from the NH <sub>2</sub> -Terminus in Type II Diabetic Patients and in Healthy Subjects", September 1995, 44: 1126-1131.   |
|  | CV  | <u>Vidal</u> , 1993, 69 <sup>th</sup> Edition, p. 612-613.  |
|  | CX  | <u>Goodman &amp; Gilman's The Pharmacological Basis of Therapeutics</u> , Ninth Edition, 1996, p. 1510.   |
|  | CY  | Nathan et al., <u>Diabetes Care</u> , "Insulinotropic Action of Glucagonlike Peptide-1-(7-37) in Diabetic and Nondiabetic Subjects", February 1992, 15(2): 270-275.   |
|  | CZ  | <u>Pschyrembel</u> , <u>Kininisches Wörterbuch</u> 257, Auflage, 1994, 9 pages.   |
|  | CAA | Frohman et al., <u>Journal of Clin. Invest.</u> , "Rapid Enzymatic Degradation of Growth Hormone-releasing Hormone by Plasma in Vitro and in Vivo to a Biologically Inactive Product Cleaved at the NH <sub>2</sub> Terminus", Volume 78, October 1986, p 906-913 |
|  | CAB | Snow et al., <u>Advances In Medicinal Chemistry</u> , "Boronic Acid Inhibitors of Dipeptidyl Peptidase IV: A New Class of Immunosuppressive Agents", Vol. 3, 1995, p 149-177.   |
| h  | CAC | Ashworth et al., <u>BIOORG. MED. CHEM. LETT.</u> , "2-Cyanopyrrolidides as Potent, Stable Inhibitors of Dipeptidyl Peptidase IV", 1996, 6(10): 1163-1166.   |

 21 Feb 2003

Demuth et al.  
09/745,776  
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Page 4 of 4



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|           | CAD | Endroczi et al., <u>ACTA PHYSIOL. HUNG.</u> , "Dipeptidyl peptidase IV (DP IV) and Superoxide Dismutase Activity in Thymus-Derived Lymphocytes: Effects of Inhibitory Peptides and Zn <sup>2+</sup> in Vitro", 1990, 75(1): 35-44. |
|           | CAE | Lee, H.S. et al., "Cathepsin B Inhibitory Peptides Derived from $\beta$ -Casein," Peptides 21 (2000) 807-809.  |
|           | CAF | Edwards, J.V. et al., <u>J. Peptide Res.</u> , "Synthesis and Activity of NH <sub>2</sub> - and COOH-Terminal Elastase Recognition Sequences on Cotton," 1999, 54: 536-543.  |
| Examiner: |     | Date: 21 Feb 2003  |